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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,480	10/23/2003	Silviu Itescu	0575/66602-B/JPW/BJA	2572

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EXAMINER	
SCHULTZ, JAMES	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/693,480	ITESCU, SILVIU	
	Examiner	Art Unit	
	J. D. Schultz, Ph.D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,14,16-20,24 and 35-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-10,14,16-20,24 and 35-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, drawn to a method of treating a disorder of a subject's heart comprising administering a composition comprising an amount of a human stromal-derived factor and human granulocyte-colony stimulating factor, classified in class 514, subclass 1. Election of this group requires the further election of a single human stromal-derieved factor-1 selected from the group consisting of 1α, 1β, and 1γ, AND a single molecule selected from the group consisting of a human granulocyte macrophage-colony stimulating factor, a human interleukin-8, a human vascular endothelial growth factor, a human fibroblast growth factor, a human Gro family chemokine, human endothelial progenitor cells, or a pro-angiogenic agent, for reasons provided below. These are not species elections. Election of this group also requires the further species election of a single disorder from the group consisting of myocardial infarction, congestive heart failure, chronic ischemia or ischemic factor, AND the further species election of a single mode of administration selected from the group consisting of intramyocardially, intracoronally, via a stent, via a scaffold or via slow release formula.

II. Claims 10, 14, 16-19, drawn to a method of treating a disorder of a tissue involving loss and/or apoptosis of cells of the tissue comprising administering a composition comprising an amount of an agent which induces phosphorylation

and/or activation of protein kinase B, classified in class 514, subclass 1. Election of this group requires the further election of a single agent selected from the group consisting of insulin, endothelin-l, urocrotin, cardiotropin-l, erythropoietin, leukemia inhibitory factor-l, and tumor necrosis factor-alpha, AND the further election of a single a human granulocyte macrophage-colony stimulating factor, a human stromal-derived factor-1, a human granulocyte macrophage-colony stimulating factor, a human interleukin-8, a human vascular endothelial growth factor, a human fibroblast growth factor, a human Gro family chemokine, human endothelial progenitor cells, or a pro-angiogenic agent, for reasons provided below. These are not species elections. Election of this group also requires the further species election of a single tissue from the group consisting of heart muscle, striated muscle, live, kidney, neuronal or gastrointestinal tissue.

III. Claim 20, drawn to a composition comprising a human stromal-derived factor-1 and a human granulocyte-colony stimulating factor, classified in class 530, subclass 351.

IV. Claim 24, drawn to a method of treating a subject suffering from a disorder of a tissue involving loss and/or apoptosis of cells of the tissue which comprises administering to the subject a composition comprising an amount of an agent which induces phosphorylation and/or activation of an extracellular signal-regulated protein kinase, the composition being administered in an amount effective to inhibit apoptosis and/or cause proliferation of the cells of the tissue

within the subject so as to thereby treat the disorder, classified in class 514, subclass 1.

V. Claims 35-37, drawn to a method of treating a subject suffering from a disorder of a tissue involving loss and/or apoptosis of cells of the tissue which comprises administering to the subject a composition comprising an amount of an agent which induces activation of CXCR4, the composition being administered in an amount effective to cause proliferation of the cells and/or inhibition of apoptosis of the cells of the tissue within the subject so as to thereby treat the disorder, classified in class 514, subclass 1. Election of this group requires the further species election of a single route of administration selected from the group consisting of intramyocardially, intracoronarily, via a stent, a scaffold, or via slow-release formulation for reasons provided below.

The inventions are distinct, each from the other because of the following reasons:

Inventions III and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process, such as using the claimed composition to investigate their roles in stimulating cardiomyocyte growth in vitro. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not

required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions I, II, IV and IV are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed each have different designs and effects, since each Group uses either a unique compound, or targets a unique target. For example, Groups I and II each use a unique combination of compounds, while Group IV targets an extracellular signal related kinase, and Group V targets CXCR4, all of which are not shared with any other Group. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Furthermore, election of Group I requires the further election of a single human stromal-derieved factor-1 selected from the group consisting of 1α, 1β, and 1γ, AND a single molecule selected from the group consisting of a human granulocyte macrophage-colony stimulating factor, a human interleukin-8, a human vascular endothelial growth factor, a human fibroblast growth factor, a human Gro family chemokine, human endothelial progenitor cells, or a pro-angiogenic agent. Group II requires the further election of a single agent selected from the group

consisting of insulin, endothelin-l, urocrotin, cardiotropin-l, erythropoietin, leukemia inhibitory factor-l, and tumor necrosis factor-alpha, AND the further election of a single a human granulocyte macrophage-colony stimulating factor, a human stromal-derived factor-1, a human granulocyte macrophage-colony stimulating factor, a human interleukin-8, a human vascular endothelial growth factor, a human fibroblast growth factor, a human Gro family chemokine, human endothelial progenitor cells, or a pro-angiogenic agent. Each such compound is related, but distinct. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are mutually exclusive owing to their unique structure, and therefore also have at least unique designs. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

The restriction requirement among the linked human stromal-derived factors, the growth factors, and the agents of Group II are each **subject to** the nonallowance of the linking generic claim(s). Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined

for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Species

This application contains claims directed to the following patentably distinct species: myocardial infarction, congestive heart failure, chronic ischemia or ischemic factor. The species are independent or distinct because each has its own unique design that does not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Each also carries its own enablement consideration, the search and examination of which are considered to constitute serious burdens on the Office.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

This application contains claims directed to the following patentably distinct species: single mode of administration selected from the group consisting of intramyocardially, intracoronally, via a stent, via a scaffold or via slow release formula. The species are independent or distinct because each has its own unique design that does not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Each also carries its own enablement consideration, the search and examination of which are considered to constitute serious burdens on the Office.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

This application contains claims directed to the following patentably distinct species: heart muscle, striated muscle, live, kidney, neuronal or gastrointestinal tissue. The species are independent or distinct because each has its own unique design that does not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Each also carries its own enablement consideration, the search and examination of which are considered to constitute serious burdens on the Office.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 10 is generic.

This application contains claims directed to the following patentably distinct species: routes of administration selected from the group consisting of intramyocardially, intracoronarily, via a stent, a scaffold, or via slow-release formulation. The species are independent or distinct

because each has its own unique design that does not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Each also carries its own enablement consideration, the search and examination of which are considered to constitute serious burdens on the Office.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 35 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. D. Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JDS

JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER